

## **REMARKS**

### **A. Status of the Claims**

Claims 1-81 were pending prior to the Office Action dated October 8, 2004. Claims 3, 4, 6, 7, 13, 14, 16, 17, 27, 28, 30, 31, and 34-35 are withdrawn from consideration.

### **B. Claims Are Not Obvious**

The Action rejects claims 1-2 and 8-9 under 35 U.S.C. § 103 as being unpatentable over WO 02/12544. Applicants traverse this rejection.

Applicants submit a declaration from the inventors under 37 CFR 1.131 to establish that the inventors invented the claimed invention before the priority date of the cited published application. *See* Exhibit 1. Consequently, WO 02/12544 does not qualify as prior art and cannot be used as the basis for an obviousness rejection. Applicants respectfully request this rejection be withdrawn.

### **C. Specification Is Amended**

Due to an error in the Sequence Listing, which Applicants corrected, minor amendment to the specification is required to address this issue. Applicants note that one of ordinary skill in the art would have readily recognized that the listing for the sequences of the nucleic acid and the amino acid of WWOX had been unintentionally switched and what was meant by statements in the specification. Applicants appreciate the Examiner's suggestion to correct the mistakes.

### **D. Limitation of 50 Contiguous Amino Acids Is Supported by the Specification**

The Action indicates that claims 8 and 18 refer to "50 contiguous amino acids" and objects to the specification as deficient because Page 56 refers only to 90 and 150 contiguous amino acids. Claim 18 does not recite this phrase, but claim 19 does, so Applicants address claims 8 and 10. This rejection is respectfully traversed.

The specification makes clear that a polynucleotide encoding 50 contiguous amino acids of SEQ ID NO:2 is contemplated. The Summary of the Invention states, “In one embodiment, the invention provides an isolated and purified polynucleotide comprising a nucleic acid encoding a WWOX polypeptide.” Page 5, lines 1-2. It also reads, “The invention also provides an expression vector comprising a nucleic acid sequence encoding a WWOX polypeptide.” Page 5, lines 15-16. At page 11 in the Summary of the Invention, the specification indicates that polypeptides of the invention include those that contain “10, 20, 30, 40, 50, 60, 70 . . . contiguous amino acids of SEQ ID NO:2.” Lines 14-18. Consequently, there is support for this phrase. Accordingly, it is respectfully requested that this rejection be withdrawn.

**E. Claims 1, 11, 25, and 32 Do Not Contain New Matter**

The Action rejects claims 1, 11, 25, and 32 as containing new matter. It alleges that the phrase “at least 20 contiguous amino acids” is not at page 56 of the specification. Applicants respectfully traverse this rejection.

On page 11 at lines 14-18 of the specification, support for phrase can be found. Applicants respectfully request this rejection be withdrawn.

**F. Claims Are Adequately Described**

The Action rejects claims 1-2, 5, 8-12, 15, 18-26, 29, 32-33, 36, and 39 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. It contends that these rejected claims are directed to a polynucleotide encoding at least [20, 50, 150] contiguous amino acids of SEQ ID NO:2 or encoding a sequence with at least 90% of the amino acids in SEQ ID NO:2 or having 99% identity with SEQ ID NO:1. The Action argues that there is insufficient written description as to whether the polypeptide encoded by the claimed polynucleotides of the rejected claims will still maintain the function of the polypeptide. Applicants respectfully traverse this rejection.

## **1. Written Description Standard**

The Federal Circuit has stated that the test for the written description requirement is “whether the application relied upon ‘reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.’” *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998). See also *Markman v. Westview Instruments, Inc.* 52 F.3d 967, 34 USPQ 2d 1321 (Fed. Cir. 1995) (en banc) (“Claims must be read in view of the specification, of which they are a part.”). In rejecting a claim under the written description requirement of 35 U.S.C. §112, first paragraph, the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined in the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

## **2. Claims Recite Structural or Chemical Properties**

The Action directs Applicants to the Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, ¶ 1 “Written Description” Requirement. Action at page 7. Those Guidelines state that the “written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.” Page 1106 (emphasis added). While a structure/function relationship may be relied upon to satisfy the written description requirement, it is not absolutely required, as suggested by in the Action.

In this case, the claim recites specific structural and chemical properties of the claimed polypeptides. Moreover, they do not recite any WWOX functional limitations. Some of the claims recite a polynucleotide that encodes at least [20, 50, 150] contiguous amino acids from SEQ ID NO:2. Other claims recite a polynucleotide that either encodes 90% of the amino acids of SEQ ID NO:2 or that has 99% identity with SEQ ID NO:1. The Action acknowledges that the amino acid sequence of SEQ ID NO:2 and the nucleic acid sequence of SEQ ID NO:1 are adequately described. Moreover, the specification fully supports the claimed polynucleotides.

In fact, from a pure mathematical point of view, the number of species disclosed by the specification with respect to each claim is numerous. For example, with respect to rejected claim 1, which recites a polynucleotide encoding a polypeptide comprising 20 contiguous amino acids from SEQ ID NO:2, a person of ordinary skill in the art would understand that the specification disclosed at least *thousands* of different species. This is true for each of the rejected claims. Even an undergraduate student who has taken an elementary molecular biology course could identify many different species that satisfied the claims based simply on the disclosed sequence. The specification provides the well-known codon chart for discerning nucleic acid sequences that fall within the scope of the claims. Page 58-59.

Based on the number of disclosed species, the specification necessarily satisfies the written description requirement because it reasonably conveys to one of skill in the art that they had possession of the claimed subject matter. *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790.

A patentee does not need to describe every embodiment on which the claim reads. According to the Federal Circuit, “[i]t is well-established that a patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the requirements of

section 112.” *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991); *see also Utter v. Hiraga*, 856 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) (“A specification may, within the meaning of 35 U.S.C. §112, paragraph 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.”).

In fact, the Guidelines on which the Action specifically relies states, “The description need only describe in detail that which is *new or not conventional*.” Page 1106 (emphasis added). The novelty of the invention lies in the sequences (full-length and partial) of SEQ ID NO:1 and SEQ ID NO:2. This is precisely what the claims are directed to—the novel portion of the invention—and this is what has been described in the application.

The written description requirement has been extensively addressed by the Federal Circuit. In particular, the Federal Circuit has stated that “[t]he written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.’” *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ 2d 1227, 1232 (Fed. Cir. 2000). The Federal Circuit has also noted that “[if] a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met.” *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996). Consequently, based on what is recited in the claims—portions of SEQ ID NO:1 or encoding portions of SEQ ID NO:2, a person of skill in the art would understand that the inventor was in possession of the claimed

subject matter based on the structural or chemical description of SEQ ID NO:1 and SEQ ID NO:2.

The basis for the rejection of the claims reciting a polynucleotide encoding 90% of the amino acids of SEQ ID NO:2 or having 99% identity with SEQ ID NO:1 is that these claims encompass “polypeptides having diverse functions.” Applicants believe this argument is irrelevant. As mentioned above, the claims do not recite a function, nor are they required to do so. Thus, whether or not a particular function is included in a particular polypeptide is not at issue with respect to the claimed invention.

Furthermore, any discussion regarding the amount of experimental research that is needed (Action at page 6) is not pertinent to the written description requirement.

As for the claims reciting a polynucleotide encoding contiguous amino acids of SEQ ID NO:1, the rejection focuses on what is located on either side of the polynucleotide and remarks that “there is no description as to where the functional domains are within SEQ ID NO:2.” As for the first comment, the claims do not require that there be anything on either or both sides. Moreover, the application makes clear that primers and probes are contemplated as part of the invention. *See e.g.*, pages 31-33. Also, Applicants again note that the description needs to describe only on what is *new or not conventional*, and the claims are described with the description of SEQ ID NO:2.

As for the comment regarding functional domains, Applicants repeat that the claims do not recite a functional requirement. The claimed polynucleotides can be used to encode polypeptides that may or may not have functional domains of SEQ ID NO:2. For example, Applicants note the extensive discussion of antibody production set forth in the specification at

pages 65-69. Nucleic acids encoding peptides and polypeptide comprising [20, 50, 150] contiguous amino acids from SEQ ID NO:2 are useful in preparing such antibodies.

In accordance with the Federal Circuit's requirements pertaining to written description, one of ordinary skill in the art would have understood that Applicants were in possession of isolated and purified polypeptides comprising 10, 20, 30, 40, 75, or 100 contiguous amino acids from SEQ ID NO:2 or SEQ ID NO:4.

### **3. Established Patent Law Requires Only That the Specification Set Forth the Invention**

The Federal Circuit in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991), cited a Supreme Court opinion that the second requirement of paragraph 112 was:

“to put the public in possession of what the part claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using . . . [the invention], of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.”

*Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822). Applicants' specification makes clear what the invention is so as to put the public on notice. There can be no dispute that they have described what they now claim. The specification and originally filed claims provide literal support for the presently rejected claims and, as discussed above, Applicants set forth structural and chemical limitations in the claims. As argued in the previous Response, this distinguishes the present situation from the case of *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). In *Eli Lilly*, the patentee claimed a human insulin cDNA but no sequence information was provided. Instead, only a way to obtain the sequence was

disclosed. In contrast, Applicants have provided the requisite chemical structures for the claimed polypeptides.

Clearly, the rejected claims recite common structural limitations—polynucleotides encoding contiguous amino acid segments, *i.e.*, peptides and polypeptides, from SEQ ID NO:2 or having a particular sequence from SEQ ID NO:1. The specification fully discloses SEQ ID NO:1 and SEQ ID NO:2.

Even if functional information were required, the specification provides relevant information regarding the WWOX polypeptide structure and its activity. In Example 1 under the subheading “WWOX protein structure,” two putative WW domains were identified as amino acids 18-47 and 59-88. A set of experiments employed the WW domains of WWOX in binding studies, as shown on page 131. Moreover, there is a discussion regarding WW domains on pages 22-24.

Additionally, FIG. 2 illustrates aspects of the WWOX structure, and in the relevant figure legend (on pages 15-16), the specification indicates that the “WW domains are boxed and conserved tryptophans and prolines are shown in bold. . . .” It also states, “The short dehydrogenase domain is underlines and the conserved residues YXXXXK and S. characteristic of a substrate binding site, are highlighted; bases GXXXGXG, typical of a coenzyme binding site, are shown in bold italics.”

The specification fully supports the claimed polynucleotides. It is respectfully requested that this rejection be withdrawn.

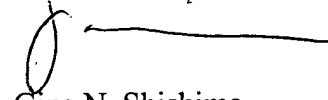
### **CONCLUSION**

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.



Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3081 is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "Gina N. Shishima", written over a horizontal line.

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